K032393

SEP 12 2003

Elcam Medical

510(k) Summary for Elcam Induction & Sampling Manifold [*or* Stopcock]

1. SPONSOR

Elcam Medical ACAL
Kibbutz BarAm
Merom HaGalil 13860
Israel

Submitter &
Contact person name: Tali Hazan – R.A Coordinator
Contact Person: Shachar Regev – Q.A Manager

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U.S AGENT

Elcam Medical, Inc.
7600 North 15th St., Suite 217
Phoenix, AZ 85020

Contact Person: Bruce Ward – General Manager

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E-mail: bward@elcam-medical.com

2. DEVICE NAME

Common/Usual Name: Induction & Sampling Manifold
Proprietary/Trade name: Induction & Sampling Manifold
Classification Name: Elcam Induction & Sampling Manifold has been classified as Class II devices under the following classification names:

Name	Product Code	21 CFR Ref.	Panel
Intravascular Administration Set	FPA	880.5440	General Hospital

CE 0483 ISO 13485 ISO 9001

3. PREDICATE DEVICES

Elcam's I&S Manifold is substantially equivalent to *Porex (KippGroup) 2 & 3 Port Manifold with back check valve*,
Part Number: MTPC-XXX-XX. 510(k) No. K000152 cleared on 29-February-2000.
It is also substantially equivalent to *Elcam's Manifold*, which was submitted by MDCI on behalf of *Elcam Plastic (Kibbutz BarAm, Merom Hagalil, Israel) *for Elcam Stopcocks and Manifolds*. 510(k) No. K022895 cleared on 03-September-2002.

* *Note:* Elcam Plastic has changed its name on January-2003 to *Elcam Medical ACAL*. No other change took place as a result of the Name Change.

4. DEVICE DESCRIPTION

All information referring *Elcam I&S Manifold* respectively refers to *Elcam I&S Stopcock* as well.
Elcam I&S Manifold is composed of a **body** that fits for number of ports assembly (by bonding) and **handles** which are assembled into the ports bodies.
Between each handle and port body an **Elastomer** is placed to function as a pressure activated valve. A small amount of **UV Adhesive** is applied in order to bond the product body to the female side ports. A **check valve** is assembled to the product body end (which is connected to the I.V Set) in order to eliminate back flow (reflux). A **Rotor** is assembled to the male luer (which is connected toward the patient) in order to enable connection locking. A small amount of **lubricant** is applied between the Elastomer and the port body.
Same concept can be available for one single Stopcock (single I&S Stopcock will not include Check Valve unless otherwise required by end user).
Elcam I&S Manifold will be available in a wide variety of configurations for use according to particular situation and the clinician's preference.

5. INTENDED USE

Elcam *Induction & Sampling Manifold* or *Stopcock* is a one or multiple ports product, which is indicated to serve as a flow control and a conduit device for I.V fluids delivery to the patient's vascular system. The product is intended for delivering I.V drugs or fluids, allowing gravity feed, sampling, bolus injection and elimination of reflux of fluids during operation.

6. TECHNOLOGICAL CARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Elcam's Induction & Sampling Manifold [or Stopcock] and *Porex (KippGroup) 2 & 3 Port Manifold with back check valve* and *Elcam's Manifold*, have the same indication for use. They have the same basic shape and use luer fittings. Elcam I&S Manifolds and Stopcocks have additional properties, which combine the two predicate devices into the Elcam I&S Manifold. Questions regarding new product safety and effectiveness were not raised due to non-identical technological characteristics.

7. PERFORMANCE TESTING

Standard testing relating functionality of the new product has been conducted on Elcam I&S Manifold, including testing related to product label claims and testing comparing performance with the predicate devices.
A biocompatibility assessment was performed on the patient-contact and fluid path materials of Elcam I&S Manifold with satisfactory results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

Elcam Medical ACAL
C/O Ms. Shachar Regev
Quality Assurance Manager
Elcam Medical, Incorporated
7600 North 15th Street Suite 217
Phoenix, Arizona 85020

Re: K032393
Trade/Device Name: Induction and Sampling Manifold (or Stopcock)
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: July 22, 2003
Received: August 8, 2003

Dear Ms. Regev:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

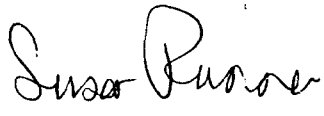
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032393

Device Name: Induction & Sampling Manifold [*or* Stopcock]

Indication for use:

Elcam *Induction & Sampling Manifold [or Stopcock]* is a one or multiple ports product, which is indicated to serve as a flow control and a conduit device for I.V fluids delivery to the patient's vascular system. The product is intended for delivering I.V drugs or fluids, allowing gravity feed, sampling, bolus injection and elimination of reflux of fluids during operation.

Silvana Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032393

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)